REMARKS/ARGUMENTS

Claims 13-16, 18-22, 26-27, 29-31, 36-42, and 47-52 remain in this application.

Rejections Under 35 USC 103

Claims 13-16, 18-22, 25-27, 29-31, 34, and 36-46 remain rejected under 35 USC 103(a) as being unpatentable over the combined disclosures of Shah et al US Patent No. 6,126,969 (the '969 Patent) in view of Sakamoto et al US Patent No. 4,828,840 (the '840 Patent). See Pages 2-5 of the Office Action. Applicants respectfully disagree.

In response to the previous arguments but forth by the Applicants, the Office Action states that "the '969 does prefer water insoluble polymers over enteric polymers, however this preference is over enteric polymers alone. Col. 4, lin. 59 – col. 5, lin. 22 discloses several enteric polymers, as well as water insoluble polymers, Eudragit methacrylate copolymers are used in the examples, these can include either enteric polymers or not. The '969 patent suggests the use of water insoluble, pH independent polymers, but does not foreclose the inclusion of enteric polymers completely." See page 6 of the Office Action. Applicants again respectfully disagree and sequentially address below each of these points.

First the Office Action states that "this preference is over enteric polymers alone." This argument assumes that the reference suggests using enteric polymers in combination with other non-enteric polymers. This is not the case. The "969 patent clearly states that it desires a "predictable rate which is independent of inter-and intra-subject physiological variations such as pH. . . . The resulting combined immediate-release/sustained-release formulation provides higher reproducibility of drug release rates than other sustained-release dosage forms utilizing conventional enteric sustained-release coating compositions . . . . (emphasis added)" See, e.g., col. 5, lines 45-60 of the '969 Patent. Thus, it clearly states a desire to avoid use enteric polymers at all, not just avoiding the use enteric polymers by itself (e.g., a particle with just an enteric polymer coating would be a delayed release particle, not a sustained release particle).

Second, the Office Action states the '969 patent discloses "several enteric polymers" and "Eudragit methacrylate copolymers are used in the examples, these can include either

enteric polymers or not." Applicants again respectfully disagree. As discussed above, the '969 Patent actually teaches away from the use of enteric polymers. Accordingly, one of ordinary skill in the art would certainly read the disclosure of methacrylate copolymers to mean the non-enteric versions of the polymer. In fact, the only specified example of an Eugragit® polymer is Eugragit® NE30D (col. 3, line 47), which is not an enteric polymer

Third, the Office Action states that "The '969 patent suggests the use of water insoluble, pH independent polymers, but does not foreclose the inclusion of enteric polymers completely." The fact that a reference does not "foreclose" on the inclusion of a claim element does not mean that it teaches or suggests the claim element. As many references fail to disclose elements of inventions, the issue with respect to obviousness is what the references actually does disclose. As stated above, the '969 Patent actually does disclose the teaching away from the inclusion of enteric polymers.

Lastly, the Office Action addresses the Applicants previous arguments regarding the claim element of "wherein the pKa of said NSAID is greater than the pH of the liquid suspension pharmaceutical dosage form." According to the Office Action, "regarding the newly added pKa limitation, as discussed above since the formulation is suspended in water (ph of 7) the ibuprofen of the particles would be more acidic having a higher pKa than the suspending liquid." See page 7 of the Office Action. This, however, is not what the Applicants were arguing.

As previously stated in the prior amendment, the Office Action fails to address why one of ordinary skill in the art, in reading the '969 Patent and the '840 Patent, would have been suggested to maintain the pH of a liquid suspension below the pKa of the NSAID (e.g., maintaining the suspension below a pH of 4.4 for particles containing ibuprofen). Applicants have found that maintaining the pH of the liquid suspension pharmaceutical dosage form lower than the pKa of the active agent inhibits the NSAID from being solubilized in the suspension, which would otherwise compromise the sustained release property of the coated particles.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5015/WEM.

Respectfully submitted,

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